### Important safety information to minimise the risk of immune-related adverse reactions

May cause some serious side effects. You may experience more than one side effect at the same time.

Contact your specialist right away if you develop any of the signs or symptoms listed below. Your doctor may give you other medicines in order to prevent more severe complications and reduce your symptoms. Your doctor may withhold the next dose of pembrolizumab or stop treatment.

For further information, consult the Patient Information Leaflet (PIL) at www.medicines.org.uk/emc or call MSD Medical Information on Tel: 01992 467272.

**IMPORTANT**
- Do not attempt to diagnose or treat side effects yourself
- Take this card with you at all times, especially when you travel, whenever you go to the Accident and Emergency department, or when you must see another doctor
- Be sure to notify any health care professional you see that you are being treated with pembrolizumab and show them this card
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine
- Complications of stem cell transplant that uses donor stem cells (allogeneic) after treatment with KEYTRUDA. These complications can be severe and can lead to death. Your doctor will monitor you for signs of these complications. Tell your transplant doctor that you have received pembrolizumab in the past

| Lungs | • Shortness of breath
|       | • Chest pain
|       | • Coughing
| Intestines | • Diarrhoea or more bowel movements than usual
|       | • Stools that are black, tarry, sticky, or contain blood or mucus
|       | • Severe stomach pain or tenderness
|       | • Nausea or vomiting
| Liver | • Nausea or vomiting
|       | • Feeling less hungry
|       | • Pain on the right side of stomach
|       | • Yellowing of skin or whites of eyes
|       | • Dark urine
|       | • Bleeding or bruising more easily than normal
| Kidneys | • Changes in the amount or colour of your urine
| Hormone glands | • Rapid heartbeat
|       | • Weight loss
|       | • Weight gain
|       | • Increased sweating
|       | • Hair loss
|       | • Feeling cold
|       | • Constipation
|       | • Deeper voice
|       | • Muscle aches
| Skin | • Rash
|       | • Itching
|       | • Skin blistering
|       | • Peeling or sores
|       | • Ulcers in mouth or in lining of nose, throat, or genital area
| Other organs | • Eyes: changes in eyesight
|       | • Muscles: pain or weakness
|       | • Heart: shortness of breath, irregular heartbeat, feeling tired, or chest pain
|       | • Pancreas: abdominal pain, nausea, and vomiting
|       | • Nerves: temporary inflammation that causes pain, weakness and paralysis in the arms and legs
|       | • Rejection of a solid organ transplant after receiving pembrolizumab (tell your doctor if you have had a solid organ transplant)
| Infusion reactions | • Shortness of breath
|       | • Itching or rash
|       | • Dizziness
|       | • Fever

⚠️ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store for how to report side effects. Adverse events should also be reported to MSD on Tel: 01992 467272.
Important Information for Health Care Providers

This patient is being treated with KEYTRUDA® (pembrolizumab), which can cause immune-related adverse reactions that involve the lungs, intestines, liver, kidneys, hormone glands, skin, and other organs, as well as infusion-related reactions. Early diagnosis and appropriate management are essential to minimise any consequences of immune-related adverse reactions.

For suspected immune-related adverse reactions, ensure adequate evaluation to confirm aetiology or exclude other causes. Based on the severity of the adverse reaction, withhold pembrolizumab and administer corticosteroids. Specific guidelines for managing immune-related adverse reactions are available in the Summary of Product Characteristics for pembrolizumab. Upon improvement to Grade 1 or less, initiate corticosteroid taper and continue to taper over at least 1 month. Consider to restart pembrolizumab if the adverse reaction remains at Grade 1 or less within 12 weeks after last dose of pembrolizumab and corticosteroid dose is ≤10 mg prednisone or equivalent per day. The safety of re-initiating pembrolizumab in patients previously experiencing immune-related myocarditis is not known. Permanently discontinue for Grade 3 or 4 myocarditis. Permanently discontinue if any Grade ≥3 toxicity occurs a second time and for any Grade 4 immune-related adverse reaction toxicity, except for endocrinopathies that are controlled with replacement hormones or haematological toxicity, only in patients with classical Hodgkin lymphoma, in whom pembrolizumab should be withheld until adverse reactions recover to Grade 0-1. Based on limited data from clinical studies in patients whose immune-related adverse reactions could not be controlled with corticosteroid use, administration of other systemic immunosuppressants can be considered.

Assess patients for signs and symptoms of pneumonitis, colitis, hepatitis, nephritis, and endocrinopathies, including hypophysitis, type 1 diabetes mellitus (including diabetic ketoacidosis), hypothyroidism, hyperthyroidism and skin adverse reactions, including Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN). Other immune-related adverse reactions reported in patients receiving pembrolizumab include: uveitis, arthritis, myositis, myocarditis, pancreatitis, Guillain-Barré syndrome, solid organ transplant rejection following pembrolizumab treatment in donor organ recipients, myasthenic syndrome, hemolytic anemia, and partial seizures arising in a patient with inflammatory foci in brain parenchyma as well as potential complications of haematopoietic allogeneic stem cell transplant in classical Hodgkin lymphoma.